



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,777	07/15/2003	William Howard Roark	PC25131A	8783

28880 7590 04/04/2006  
WARNER-LAMBERT COMPANY  
2800 PLYMOUTH RD  
ANN ARBOR, MI 48105

EXAMINER

OLSON, ERIC

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,777	<b>Applicant(s)</b> ROARK, WILLIAM HOWARD	
	<b>Examiner</b> Eric S. Olson	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **Detailed Action**

This application is a non-provisional application of provisional application 60/396922, filed July 17, 2002. Claims 1-10 are pending in this application and examined on the merits herein.

### **Restriction/Election**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5 in part, drawn to a combination comprising valdecoxib with a compound of formula IC in  $X_1$ ,  $X_2$ , and  $X_3$  all independently represent  $C-R_6$ , and there is no fused tricyclic ring system, classified in class 544, subclass 283, for example.
- II. Claims 1-5 in part, drawn to a combination comprising valdecoxib with a compound of formula IC in which exactly one of  $X_1$ ,  $X_2$  and  $X_3$  represents N, and the other two of  $X_1$ ,  $X_2$  and  $X_3$  independently represent  $C-R_6$ , and there is no fused tricyclic ring system, classified in class 544, subclass 279, for example.
- III. Claims 1-2 and 5 in part, drawn to a combination comprising valdecoxib with a compound of formula IC in which exactly two of  $X_1$ ,  $X_2$  and  $X_3$  represent N, and the other one of  $X_1$ ,  $X_2$  and  $X_3$  represents  $C-R_6$ , and there is no fused tricyclic ring system, classified in class 544, subclass 236 or 256, for example.

Art Unit: 1623

IV. Claims 1 and 3-5 in part, drawn to a combination comprising valdecoxib with a compound of formula IC in  $X_1$ ,  $X_2$ , and  $X_3$  all independently represent C-R<sub>6</sub>, and W<sub>1</sub>-W<sub>2</sub> are part of a five-membered ring, classified in class 544, subclass 251, for example.

V. Claims 1 and 5 in part, drawn to a combination comprising valdecoxib with a compound of formula IC in which exactly one of  $X_1$ ,  $X_2$  and  $X_3$  represents N, and the other two of  $X_1$ ,  $X_2$  and  $X_3$  independently represent C-R<sub>6</sub>, and W<sub>1</sub>-W<sub>2</sub> are part of a five-membered ring, classified in class 544, subclass 251, for example.

VI. Claims 1 and 5 in part, drawn to a combination comprising valdecoxib with a compound of formula IC in which exactly two of  $X_1$ ,  $X_2$  and  $X_3$  represent N, and the other one of  $X_1$ ,  $X_2$  and  $X_3$  represents C-R<sub>6</sub>, and W<sub>1</sub>-W<sub>2</sub> are part of a five-membered ring, classified in class 544, subclass 234 or 251, for example.

VII. Claims 6-10, drawn to a method of treating a disease comprising administering a therapeutically effective dose of a combination of valdecoxib and an allosteric carboxylic inhibitor of MMP-13, classified in class 514, subclass 248, 249, 250, 262.1, 264.1, 264.11, and 266.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are separate and patentably distinct in view of being drawn to combinations comprising structurally distinct compounds. The MMP-13

inhibitors included in the various groups have unrelated structures and thus raise different issues of patentability. Each group possess a unique core structure which sets it apart as a separate invention, as illustrated by the structures listed in Figure 1. A reference anticipating or rendering obvious one member will not anticipate or render another obvious. This difference is illustrated by the separate classifications of the MMP-13 inhibitors in each group. A chemical structure or name search for more than one of the aforementioned groups in a single application would be unreasonably broad and would require separate searches of the chemical literature for each group and impose an undue search burden on the Office.

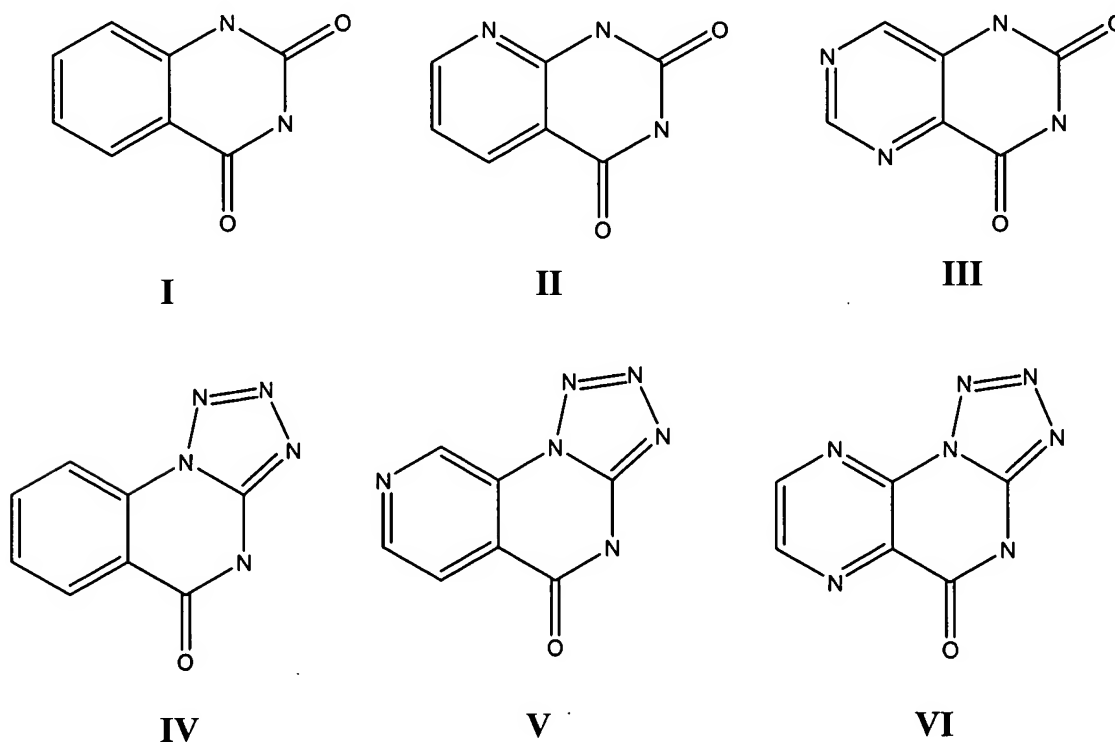


Figure 1 - Examples of core structures falling within each group

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as recognized by their different classifications, restriction for examination purposes as indicated is proper.

Inventions I-VI are related to invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of claim IX could be practiced with another materially different product, including other non-steroidal anti-inflammatory drugs such as ibuprofen or naproxen for treatment of inflammatory arthritis and joint pain.

The search field for a composition is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103 because a search indicating the process or method is novel or unobvious would not extend to a holding that the product is novel or unobvious whereas a search indicating that the product is known or would have been obvious would not extend to a holding that the process or method is known and would have been obvious. Note that the search is not

Art Unit: 1623

limited to patent files. Thus an undue burden on the Office is seen for the search of all inventions herein, as discussed in the Requirement for Restriction above.

Because these inventions are distinct for the reasons given above and the search required for Group VII is not required for Groups I-VI, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Note that as the process claims in group VII do not depend from any product claims and include only the limitations of claim 5, rejoinder will only be allowed in the event that claim 5 is found to be allowable. Allowance of any of claims 1-4 will not entitle the Applicant to rejoinder.

Because the above restriction requirement is complex, a telephone call to applicant's agent to request an oral election was not made. (See MPEP 812.01)

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday through Friday from 8:30-5:00.

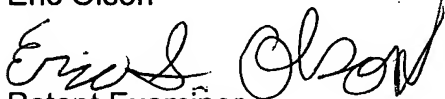
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Olson



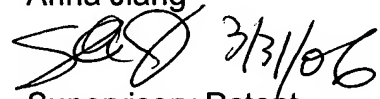
Patent Examiner

Examiner

AU 1623

3/29/06

Anna Jiang



Supervisory Patent

AU 1623